PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Levon ARAKELYAN, et al.

Appln. No.: 10/662,345

Confirmation No.: 2068

Filed: September 16, 2003

Docket No: Q71975

Group Art Unit: 1631

Examiner: Not Yet Assigned

For: AN INTERACTIVE TECHNIQUE FOR OPTIMIZING DRUG DEVELOPMENT FROM THE PRE-CLINICAL PHASES THROUGH PHASE-IV

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98

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In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents, other than any U.S. patents and patent publications, is submitted herewith.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,

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Sheet 1 of 1

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Application Number	
Filing Date	Sept. 16, 2003
First Named Inventor	Levon ARAKELYAN
Art Unit	
Examiner Name	
Attorney Docket Number	Q71975

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 6,041,788 B1	03-28-2000	Liji Shen	
		US- 5,657,255 B1	08-12-1997	Fink et al	
		US- 5,808,918 B1	09-15-1998	Fink et al	
		US- 6,081,786 B1	06-27-2000	Barry et al	
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FOREIGN PATENT DOCUMENTS						
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		WO 02/051354 A2	07-04-2002	Robert Becker		
		WO 97/44752 A1	11-27-1997	Kornman et al		
		WO 01/00083 A1	01-04-2001	Thomas et al		

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	1.	FDA, CENTER FOR DRUG EVALUATION AND RESEARCH (CDER), Drug Development Process for Investigational New Drugs, http://www.fda.gov/cder/handbook/develop.htm, pp.3-28	
	2.	DEPARTMENT OF HEALTH AND HUMAN SERVICES, FDA, International Conference on Harmonization: Guidance on General Considerations for Clinical Trials, Federal Register Wednesday, December 17, 1997, pp. 66113-66119, Vol. 62, No. 242	
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	21	R. MEHR et al, Temporal stochasticity leads to nondeterministic chaos in a model for blood cell production. in: "Fluctuations and Order:The New Synthesis", 1996, pp. 419-427, Springer, New-York	
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	38	D. BERRY, Adaptive Trials and Bayesian Statistics in Drug Development, Biopharmaceutical Report, 2001, pp. 1-11 vol. 9(2) ✓	
	39	D. BERRY, General Keynote: Clinical Trial Design, Gynecological Oncology, 2003, pp. S114-S116, vol. 88 ✓	
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